IFU

Instructions for Use

CRITERION™ D/E NEUTRALIZING BROTH

Cat. no. C7370	CRITERION™ D/E Neutralizing Broth	84.8gm
Cat. no. C7371	CRITERION™ D/E Neutralizing Broth	500gm
Cat. no. C7372	CRITERION™ D/E Neutralizing Broth	2kg
Cat. no. C7373	CRITERION™ D/E Neutralizing Broth	10kg
Cat. no. C7374	CRITERION™ D/E Neutralizing Broth	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ D/E Neutralizing Broth is an employed for neutralizing of antiseptics and disinfectants and detecting organisms remaining after treatment. This broth is especially suited for environmental sampling where neutralization of the chemical is important to determine its bactericidal activity.

This dehydrated culture medium is a raw material intended to be used in the making of prepared media products, which will require further processing, additional ingredients, or supplements.

SUMMARY

D/E Neutralizing Broth, also known as Dey-Engley Neutralizing Broth, is capable of neutralizing a broad spectrum of antiseptic and disinfectant chemicals including ethanol, quaternary ammonium compounds, phenolics, iodine, chlorine preparations, mercurials, formaldehyde and glutaraldehyde. It can determine the bactericidal capability of disinfectants and therefore is well suited for environmental sampling (swab and contact plate methods).

Complete neutralization of disinfectants is important because disinfectant carryover can cause a false no-growth test result. D/E Neutralizing media effectively neutralizes the inhibitory effects of disinfectant carryover, allowing differentiation between bacteriostasis and the true bactericidal action of disinfectants.

FORMULA

Gram weight per liter:	39.02gm/L
Dextrose	10.0gm
Lecithin	7.0gm
Sodium Thiosulfate	6.0gm
Pancreatic Digest of Casein	5.0gm
Tween® 80	5.0gm
Yeast Extract	2.5gm

Sodium Bisulfite	2.5gm
Sodium Thioglycollate	1.0gm
Bromcresol Purple	0.02gm

Final pH 7.6 +/- 0.2 at 25ºC.

* Adjusted and/or supplemented as required to meet performance criteria.

STORAGE AND SHELF LIFE

Store the sealed bottle(s) containing culture medium at 2-8ºC. Protect dehydrated culture media from moisture and light. The dehydrated culture media should be discarded if it is not homogenous, moist, and lumpy or if the color has changed from its original bluish-gray.

Store the prepared culture media at 2-8ºC.

The expiration date on the product label applies to the product in its intact packaging when stored as directed. The product may be used and tested up to the expiration date on the product label and incubated for the recommended incubation times as stated below.

Refer to the document "Storage" for more information.

PRECAUTIONS

This product may contain components of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not guarantee the absence of transmissible pathogenic agents. Therefore, it is recommended that these products be treated as potentially infectious, and handle observing the usual universal blood precautions. Do not ingest, inhale, or allow to come into contact with skin.

This product is for laboratory use only. It is to be used only by adequately trained and qualified laboratory personnel. Observe approved biohazard precautions and aseptic techniques. All laboratory specimens should be considered infectious and handled according to "standard precautions." Refer to the document "Guidelines for Isolation Precautions" from the Centers for Disease Control and Prevention.

For additional information regarding specific precautions for the prevention of the transmission of all infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to infectious disease, refer to CLSI document M29: *Protection of Laboratory Workers from Occupationally Acquired Infections.*

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information.

METHOD OF PREPARATION

1. Suspend the 42.4gm of the dehydrated culture media in 1 liter of distilled or deionized water.

2. Heat to boiling and mix to dissolve completely to obtain an even suspension.

3. Dispense appropriate amount of the broth media into tubes.

4. Sterilize in the autoclave at 121ºC. for 15 minutes.

PROCEDURE AND INTERPRETATION OF RESULTS

For information on procedures and interpretation of results, consult listed references or refer to the prepared media

Instructions for Use (IFU) for Cat. No. U75.

LIMITATIONS

It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on colonies from pure culture for complete identification.

Some formulations may require a settling period before pH testing of the prepared medium. If the pH is tested immediately after preparation and is out of specification, retest the medium after 24 hours to obtain final pH results. Always take pH reading at room temperature.

Refer to the document "Limitations of Procedures and Warranty" for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as autoclaves, incinerators, and incubators, etc., are not provided.

QUALITY CONTROL

Hardy Diagnostics tests each lot of commercially manufactured media using appropriate quality control microorganisms and quality specifications as outlined on the Certificate of Analysis (CofA) and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media*. The following microorganisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	
Bacillus spizizenii ATCC® 6633	A	40-48hr	35°C	Aerobic	Growth; usually no color change
Escherichia coli ATCC® 25922	A	40-48hr	35°C	Aerobic	Growth; yellow color change
Pseudomonas aeruginosa ATCC® 9027	A	40-48hr	35°C	Aerobic	Growth; no color change
Salmonella enterica ATCC® 14028	A	40-48hr	35°C	Aerobic	Growth; yellow color change
Staphylococcus aureus ATCC® 6538	A	40-48hr	35°C	Aerobic	Growth; yellow color change

* Refer to the document "Inoculation Procedures for Media QC" for more information.

USER QUALITY CONTROL

Users of dehydrated culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements. Hardy Diagnostics recommends end users check for signs of contamination and deterioration and, if dictated by laboratory quality control procedures or regulation, perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction, if applicable. Hardy Diagnostics quality control testing is documented on the certificate of analysis (CofA) available from Hardy Diagnostics Certificate of Analysis website. In addition, refer to the following document "Finished Product Quality Control Procedures," for more information on QC or see the reference(s) for more specific information.

PHYSICAL APPEARANCE

CRITERION™ D/E Neutralizing Broth powder should appear moist, lumpy, and bluish-gray in color. The prepared media should appear opaque, with an even suspension of particulates, and gray-purple to purple in color.

REFERENCES

1. FDA. 1995. *Bacteriological Analytical Manual*, 8th ed. FDA.

2 Marshall, R.T., ed. 1992. *Standard Methods for the Examination of Dairy Products*, 16th ed. APHA, Washington, D.C.

3 Vanderzant, C. and D.F. Splittstoesser, (ed.). 1992. *Compendium of Methods for the Microbiological Examination of Foods*, 3rd ed. APHA, Washington, D.C.

4 Greenberg, A.E., et al. (ed.). 1992. *Standard Methods for the Examination of Water and Wastewater*, 18th ed. APHA, Washington, D.C.

5. *U.S. Pharmacopeia*, 22nd rev. 1990. U.S. Pharmacopeial Convention, Rockville, MD.

IFU-10146[C]

1430 West McCoy Lane, Santa Maria, CA 93455, USA
Phone: (805) 346-2766 ext. 5658
Fax: (805) 346-2760
Website: HardyDiagnostics.com
Email: TechnicalServices@HardyDiagnostics.com
Ordering Information

Distribution Centers:
California · Washington · Utah · Arizona · Texas · Ohio · New York · Florida · North Carolina

The Hardy Diagnostics manufacturing facility and quality management system is certified to ISO 13485.

HDQA 2207B [D]